K120281

SEP 17 2012

Section 5 **510(k) Summary**

Dignity® Power Injectable Titanium Port
Summary of Safety and Effectiveness
Prepared January 30, 2012

General Information

Submitter: MEDCOMP®
1499 Delp Drive
Harleysville, PA 19438
Phone: (215) 256-4201
Fax: (215) 256-9191

Contact: Rosanna Severini
Compliance Manager

Device Trade Name: Dignity® Power Injectable Titanium Port
Common Name: Power Injectable, Implantable, Infusion Port
Classification Name: LJT - Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Long-Term, Greater than 30 Days
CFR Reference: 21 CFG 880.5965, Class II
Classification Panel: General Hospital

Predicate Devices:

Device Trade Name: Power Injectable Implantable Port
Common Name: Implanted Infusion Port & Catheter
Classification Name: LJT – Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Long-Term Greater than 30 Days
CFR Reference: 21 CFR 880.5965, Class II
Classification Panel: General Hospital
Premarket Notification: K070003, Medcomp, Inc, concurrence date May 15, 2007

Device Trade Name: CT Power Injectable Implantable Port
Common Name: Implanted Infusion Port & Catheter
Classification Name: LJT – Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Long-Term Greater than 30 Days
CFR Reference: 21 CFR 880.5965, Class II
Classification Panel: General Hospital
Premarket Notification: K11424, Medcomp, Inc, concurrence date November 30, 2011

Device Trade Name: C-Port ^{HP} "Power Injectable" Port
Common Name: Implanted Infusion Port & Catheter
Classification Name: LJT – Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Long-Term Greater than 30 Days
CFR Reference: 21 CFR 880.5965, Class II
Classification Panel: General Hospital
Premarket Notification: K091099, PHS Medical GmbH

Intended Use:

The totally implanted titanium port is indicated for patient therapies requiring repeated access to the vascular system.

Indications for Use:

The CT Power Injectable Implantable Infusion Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the Power Injectable Implantable Infusion Port device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.

Device Description:

- Titanium port designed for subcutaneously implantable single fluid reservoir port offered in a mid-size, low profile or mini version with a 5F, 6.6F, 8F or 9.6French radiopaque polyurethane or silicone catheter either pre-attached by the manufacturer or attachable for application by the inserting physician.
- Placement of the port is determined by the inserting physician based on patient anatomy and medical judgment.
- The port can be anchored with sutures in the port pocket for secure seating.
- The catheter lock provides securement of the catheter to the port stem.
- The port is accessed by inserting a non-coring needle through the skin into the self sealing septum.
- Port base has radiopaque text "CT" on the underside visible by x-ray
- Lot numbers are laser etched into the base of the port.
- Power injection of contrast media, can be safely administered with a 19 or 20 gauge power injectable infusion non-corning needle at a maximum recommended infusion rate of 5 ml/s. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.
- The device is recognized as part of the Medcomp power injectable product line by its anodized purple titanium housing.
- CT and MR compatible
- The port is compatible with non-coring Huber deflected point septum penetration style needles.

Biocompatibility

Biocompatibility requirements of *ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* for externally communicating, blood contacting, long-term devices were met.

Technological Characteristics

Technological characteristics of the subject device with a polyurethane catheter are equivalent to those of the predicated devices. This equivalence extends to basic design,

generic materials, and construction. The distinguishing difference exists in the reduced size of the subject port body.

In vitro testing was performed on the Power Injectable, Implantable Infusion Port to assure reliable design and performance in accordance with the FDA's "Guidance on 510(k) Submissions for Implanted Infusion Ports" dated October 1990. Verification testing and performance testing performed according to the referenced standards as well as in accordance with in-house protocols.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices. This device presents no known additional risks to the patient that are not well documented and for which there is already a prescribed therapy.

Safety & Performance Tests

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. Design verification testing was performed according to protocols based on the recommendations and requirements of applicable FDA guidance and FDA recognized international standards. Verification testing, determined to be applicable to the safety and efficacy of the devices, was shown to meet predetermined acceptance criteria listed therein.

Risk Management of the subject device was conducted in accordance with an internal protocol based on ISO 14971: 2000, *Medical Devices – Risk Management for Medical Devices.* The analysis did not identify any new types or safety or efficacy questions for the proposed device.

The results of these tests, in conjunction with the substantial equivalence claims effectively demonstrate that Dignity® TI CT Rated Port is substantially equivalent to the cited predicate devices.

Summary of Substantial Equivalence

Based on the indications for use and safety and performance testing, the Dignity® Power Injectable Titanium Ports meets the requirements that are considered for its intended use and is substantially equivalent in design materials, sterilization, and indications for use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 17 2012

Medical Components Incorporated
Ms. Rosanna Severini
Regulatory Specialist
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K120281
Trade/Device Name: Dignity® Power Injectable Titanium Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: August 3, 2012
Received: August 6, 2012

Dear Ms. Severini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120281

Device Name: Dignity® Power Injectable Titanium Port

Indications for Use:

The CT Power Injectable Implantable Infusion Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the Power Injectable Implantable Infusion Port device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/12/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120281